# In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 13-691V

(Not to be Published)

| * | * * |                          |
|---|-----|--------------------------|
|   | *   |                          |
| AMERICO E. GAMBO, as Personal           | *   |                          |
| Representative of the Estate of         | *   |                          |
| FRANCES CHAMBERS GAMBO, deceased,       | *   |                          |
| , ,                                     | *   | Filed: December 18, 2014 |
| Petitioner,                             | *   | ,                        |
| ,                                       | *   |                          |
| V.                                      | *   | Fact Ruling; Proof of    |
|   | *   | Vaccination; Influenza   |
| SECRETARY OF HEALTH AND                 | *   | ("Flu") Vaccine          |
| HUMAN SERVICES,                         | *   |                          |
| ,                                       | *   |                          |
| Respondent.                             | *   |                          |
| 1                                       | *   |                          |
| * | * * |                          |

Danielle E. Strait, Maglio Christopher & Toale, PC, Washington, D.C., for Petitioner.

Lisa A. Watts, U.S. Dep't of Justice, Washington, D.C., for Respondent.

### FACT RULING ON PROOF OF VACCINATION<sup>1</sup>

#### CORCORAN, Special Master

In this petition, initially filed on September 17, 2013, Americo Gambo (representative of the deceased vaccinee, Frances Chambers Gambo (Mr. Gambo's spouse)) seeks to establish that the influenza ("flu") vaccine that Mrs. Gambo received in October of 2010 caused her to develop some form of demyelinating injury which in turn resulted in her death on December 4, 2011. However, Petitioner has been unable to locate documentary proof of vaccination, and now moves

<sup>&</sup>lt;sup>1</sup> Because this ruling contains a reasoned explanation for my action in this case, it will be posted on the website of the United States Court of Federal Claims in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the inclusion of certain kinds of confidential information. To do so, Vaccine Rule 18(b) provides that each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the ruling will be available to the public. *Id*.

(based on circumstantial evidence) for a fact finding that Mrs. Gambo did receive the flu vaccine in October 2010. After my review of the evidence submitted and the parties' briefs, I find that Petitioner has established adequate proof of vaccination.

### I. Factual Background

Petitioner alleges that Mrs. Gambo received a flu vaccine "in or about" October of 2010 somewhere in Maryland, although the precise circumstances surrounding her receipt of that vaccination are clouded. *See* Amended Petition (ECF No. 14-1) at ¶ 1. By early January of 2011, Mrs. Gambo went to her primary care physician, Dr. Anthony Serafis, in Lutherville, Maryland, complaining of having experienced numbness and shooting pains in her feet for the prior month, and also reported having experienced numbness in her hands over the week prior to her appointment. Ex. 8 at 5. Later medical records similarly record Mrs. Gambo's complaints of paresthesias in her hands and feet that began sometime after Thanksgiving in 2010. Ex. 7 at 830. Around that time, a treating physician opined that Mrs. Gambo's symptoms suggested she might be experiencing some kind of peripheral neuropathy. Ex. 8 at 5. After additional evaluation in 2011, Mrs. Gambo was eventually diagnosed with Guillain-Barré syndrome ("GBS") and then later Chronic Inflammatory Demyelinating Polyneuropathy. Her health deteriorated throughout the year until her death on December 4, 2011. Ex. 2.

Petitioner has been unable to offer direct proof of Mrs. Gambo's receipt of vaccination. Instead, he has provided circumstantial evidence that, taken together, provides a narrative by recollection to establish that the flu vaccine was administered to Mrs. Gambo. Thus, Petitioner has offered his own affidavit in which he swears under penalty of perjury that his wife informed him of her receipt of the flu vaccination sometime in October 2010. See Affidavit of Americo Gambo, dated May 16, 2014 (attached to ECF No. 26) ("Gambo Aff.") at ¶¶ 6-7. He specifically recalls this because it was around the time of the Gambos's wedding anniversary (and, in fact, he avers that Mrs. Gambo told him the vaccination was an anniversary gift to him). Id. He also references numerous instances in Mrs. Gambo's medical records that refer to the vaccination as having occurred. See Petitioner's Motion for Finding of Fact, dated September 29, 2014 (ECF No. 36) at 4-7.

In addition, Petitioner has offered two statements from a physician, Dr. Elizabeth Schlenoff that supports his contention that Ms. Gambo received the vaccination in question. Although Dr. Schlenoff was not Mrs. Gambo's primary care physician, the medical records corroborate that she sent Mrs. Gambo for certain testing (including an MRI) in early 2011, contemporaneously with the time Mrs. Gambo first saw her primary care physician, Dr. Serafis, regarding the symptoms that she was experiencing. *See* generally Ex. 8.

The first is an unsworn statement dated July 15, 2014. Ex. 12 (ECF No. 34). In it, Dr. Schlenoff states that she recalls seeing Mrs. Gambo as a patient at some unspecified time and that she considered Mrs. Gambo's condition to be "stunning" from a neurologic standpoint. *See generally* Letter, dated July 15, 2014 (ECF No. 34). She also specifically recalls receiving by facsimile transmission proof of the vaccination in question from a pharmacy, and placing it in Ms. Gambo's chart, but she was unable to locate the record in her files, which are presently maintained in her home. *Id*.

The second statement comes in the form of a declaration, which provides more detail about the context in which Mrs. Gambo saw Dr. Schlenoff. See December 2, 2014 declaration (ECF No. 40) ("Schlenoff Declaration"). Dr. Schlenoff notes in it that she was Petitioner's primary care physician, rather than Mrs. Gambo's, but (after learning from him of Mrs. Gambo's illness) saw Mrs. Gambo in January 2011 and was responsible for sending Mrs. Gambo for some of the neurologic testing that later resulted in her GBS diagnosis. Schlenoff Declaration at ¶¶ 5-8. In the course of filing some old medical records in March 2011, Dr. Schlenoff indicated that she came across a physical document from a local pharmacy memorializing Mrs. Gambo's receipt of vaccination. Id. at ¶ 9. Dr. Schlenoff speculates that the pharmacy may have mistakenly sent her the proof of vaccination based upon her existing doctor-patient relationship with Mr. Gambo. Id.

#### II. Procedural History

After filing the petition in September of 2013, Mr. Gambo filed documents certifying his legal status as the representative of Mrs. Gambo's estate. *See* ECF No. 4 & 6. He subsequently filed a number of medical records, while attempting via subpoena to obtain additional records not in his possession. *See*, *e.g.*, ECF No. 17 & 20.

On May 28, 2014, Petitioner filed a Statement of Completion (ECF No. 28), but in so doing acknowledged that proof of vaccination was still elusive. The next day, Mr. Gambo moved to strike the May 28th filing, noting that he had learned of the existence of Dr. Schlenoff, who likely possessed records substantiating the vaccination. ECF No. 29. Thereafter, from June until August of this past summer, Petitioner continued his efforts to obtain such evidence, requesting the issuance of an additional subpoena for this purpose. See ECF No. 29 & 32.

On September 29, 2014, Petitioner filed the present motion based on the record he had been able to generate (ECF No. 36), and Respondent opposed the motion on October 6, 2014 (ECF No. 38). During an October 30, 2014 status conference, I requested that Petitioner supplement the existing record in support of his motion – mainly by obtaining a more detailed statement from Dr. Schlenoff to fill in some of the blanks in Petitioner's narrative. ECF No. 39. Petitioner subsequently filed a declaration from Dr. Schlenoff on December 2, 2014 (ECF No.

40), and then I held a follow-up status conference on December 10, 2014, during which Respondent declined to further address the merits of the matter and requested that I issue a ruling. This matter is now ripe for adjudication.

#### III. Analysis

A Vaccine Act petitioner must, as a threshold matter in advancing a claim for damages, establish by a preponderance of the evidence receipt of "a vaccine set forth in the Vaccine Injury Table." § 300aa–11(c)(1)(A). The preponderance of the evidence standard means that an allegation is established to be "more likely than not." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010).

Although contemporaneous documentation of vaccination from a healthcare provider is the best evidence that a vaccination occurred, it is not absolutely required in all cases. *Centmehaiey v. Sec'y of Health & Human Servs.*, 32 Fed. Cl. 612, 621 (1995) ("[t]he lack of contemporaneous documentary proof of a vaccination . . . does not necessarily bar recovery"). Indeed, as Vaccine Rule 2 states, "[i]f the required medical records are not submitted, the petitioner must include an affidavit detailing the efforts made to obtain such records and the reasons for their unavailability." Vaccine Rule 2(c)(2)(B)(i). Furthermore, if a petitioner's claim is "based in any part on the observations or testimony of any person, the petitioner should include the substance of each person's proposed testimony in a detailed affidavit(s) supporting all elements of the allegations made in the petition." Vaccine Rule 2(c)(2)(B)(ii).

Special masters have thus found that vaccine administration occurred even in the absence of direct documentation. In such cases, preponderant evidence was provided in the form of other medical records and/or witness testimony. For example, corroborative, though backward-looking, medical notations have been found to tip the evidentiary scale in favor of vaccine receipt. *Lamberti v. Sec'y of Health & Human Servs*, No. 99–507V, 2007 WL 1772058, at \*7 (Fed. Cl. Spec. Mstr. May 31, 2007) (finding multiple medical record references to vaccine receipt constituted adequate evidence of administration); *Groht v. Sec'y of Health & Human Servs*, No. 00–287V, 2006 WL 3342222, at \*2 (Fed. Cl. Spec. Mstr. Oct. 30, 2006) (finding a treating physician's note—"4/30/97—Hep B. inj. # 1 (not given here) (pt. wanted this to be charted)"—to be sufficient proof of vaccination); *Wonish v. Sec'y of Health & Human Servs*., No. 90–667V, 1991 WL 83959, at \*4 (Cl. Ct. Spec. Mstr. May 6, 1991) (finding parental testimony "corroborated strongly by medical records [referring] back to the [vaccination]" to be sufficient to establish vaccine administration).

In addition to corroborative medical records, witness testimony can also help establish a sufficient basis for a finding that a vaccine was administered as alleged. *Alger v. Sec'y of Health* 

& Human Servs, No. 89–31V, 1990 WL 293408, at \*2, 7 (Fed. Cl. Spec. Mstr. Mar. 14, 1990) (oral testimony from a parent and the doctor who administered the vaccine was "more than adequate to support a finding that the vaccine was administered"). The Court of Federal Claims has recognized the existence of precedent supporting the proposition that a court may base a finding of vaccination on lay testimony. Epstein v. Sec'y of Health & Human Servs., 35 Fed. Cl. 467, 478 (Fed. Cl. 1996); see also Brown v. Sec'y of Health & Human Servs., 18 Cl. Ct. 834, 839–40 (1989) (proof of vaccination in the absence of contemporaneous medical records established via testimony of petitioner's parent, her personal calendar, and evidence of a charge for the vaccine on the physician's billing statement), rev'd on other grounds, 920 F.2d 918 (Fed. Cir. 1990).

In the present case, Petitioner has marshaled ample circumstantial evidence in support of his contention that Mrs. Gambo more likely than not received the flu vaccine in October of 2010. He has identified multiple references in Mrs. Gambo's treatment record that not only mention the prior vaccination but also link it to her illness as a possible cause. In addition, Petitioner has offered his own affidavit in which he swears under penalty of perjury that his wife informed him of her vaccination. I find that Mr. Gambo has provided a plausible explanation for why he remembers her telling him of the vaccination (*i.e.*, the fact that the Gambos's anniversary was around the same time, and he had previously urged her to obtain a flu vaccine).

The statements from Dr. Schlenoff bulwark the above. She avers to have seen a physical copy of the vaccination record (although she has no contemporaneous knowledge of the actual vaccine administration). Although Dr. Schlenoff was only involved in Mrs. Gambo's care to a limited extent, she observed her symptoms around the time Mrs. Gambo visited Dr. Serafis, and Dr. Schlenoff's role in Mrs. Gambo's treatment is corroborated by the medical record.

Respondent raises some reasonable objections to this evidence generally. The medical record contains no references to the vaccination before the spring of 2011, and it does not appear that Mrs. Gambo told Dr. Serafis or Dr. Schlenoff that she received the vaccination. But there are many backward-looking references to the vaccination in the recorded treatment history, suggesting that Mrs. Gambo or Petitioner recounted the fact to the treating physicians. In addition, Petitioner has offered statements from two third parties – himself and Dr. Schlenoff – that taken together provide additional circumstantial support that Respondent has not rebutted. Accordingly, there is therefore enough circumstantial evidence in the record to suggest that Mrs. Gambo received a flu vaccination in the month Petitioner alleges.

I do not find, however, that Petitioner has established a precise date or half of the month when the vaccination actually occurred. As Respondent points out, the sole evidence offered to establish this aspect of Petitioner's argument is Mr. Gambo's affidavit, in which he recalls a hearsay statement made by Mrs. Gambo about having received the vaccination. While I am

willing to credit Mr. Gambo's overall recollection of the fact of vaccination, there remains insufficient evidence to pinpoint a precise date in October when the vaccination was administered. Indeed, at best Mr. Gambo's affidavit only establishes that he *learned* of the vaccination in the second half of October 2010. Gambo Aff. at ¶ 6. He surmises it occurred during that time period because of the date of their anniversary, but the basis for his hunch ("the way she phrased it") is too insubstantial to rely upon, especially in the absence of any other corroborative proof.

#### **CONCLUSION**

Based upon my review of the record, including the affidavits and witness statements, and the legal arguments of the parties, I find that Petitioner has established by preponderant evidence that Mrs. Gambo received the influenza vaccination on an unspecified date in October 2010. Petitioner has thus satisfied his burden as to receipt of a vaccine listed on the Vaccine Injury Table within the United States. *See* 42 U.S.C. § 300aa11(C)(1)(A) and (B).

This ruling makes no determination of any kind as to whether Mrs. Gambo's alleged damages are a result of an adverse reaction to the flu vaccination. That will be the subject of future proceedings.

IT IS SO ORDERED.

/s/ Brian H. Corcoran Brian H. Corcoran Special Master